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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,105	04/23/2001	Pal Maliga	RUT 00-0010	8371

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EXAMINER
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KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/17/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/762,105

Applicant(s)

MALIGA ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2002 and 16 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

***Election/Restrictions***

1. The restriction requirement mailed 6 May 2002 is withdrawn in favor of the restriction requirement below.
2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a DNA construct for expressing a heterologous protein in plastids, wherein the construct comprises a 5' regulatory region, a leader sequence and a downstream box element.

Group II, claim(s) 15-17, all in part, drawn to a plastid transformation vector.

Group III, claim(s) 15-17, all in part, and 24-~~26~~, drawn to a method for transforming rice plastids, wherein embryogenic calli are induced on modified CIM medium and then bombarded with plasmid DNA, and plants so produced.

Group IV, claim(s) 18-23, drawn to a method for transforming monocot plastids, wherein the method comprises exposing cells to a heterologous DNA molecule encoding a selectable marker, and plants so produced.

Group V, claim(s) 27-28, drawn to a method for modifying codon usage in structural genes.

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The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The inventions of groups I-IV, drawn to plastid transformation constructs or methods, do not share a technical feature with the invention of Group V, drawn to a method for modifying codon usage in structural genes. The method of Group V would not make the product of any of Groups I-IV.

The technical feature shared by Groups I-IV is constructs for plastid transformation and methods of performing that transformation. However, this technical feature is not special. Zoubenko et al (1994, Nuc. Acids Res. 22:3819-3824; cited in the Written Opinion) teach a chloroplast expression vector comprising a recombinant construct comprising an *rrn* 5' regulatory region and a heterologous *aadA* gene encoding a spectinomycin resistance protein (pg 3820, left column, paragraphs 3-4), wherein the promoters and constructs would inherently comprise the native leader sequence and downstream box element, and methods of plastid transformation. Thus, claim 1, among others, not novel, and the technical feature shared by Groups I-IV is not special.

3. Different nucleotide sequences are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434).

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If Applicant elects Group I, Applicant is additionally required to select a single nucleotide sequence for said Group. If Applicant elects Group II or III, Applicant is required to select a single plasmid for said Group. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

It is not clear if any of the plasmids of Groups II and III use any of the regulatory regions of Group I. If Applicant elects Group I, and points out which plasmid(s) of Group II or Group III contains that element and if the plasmids of Groups II and III also have all the other elements of the DNA constructs of claim 1, the groups can be rejoined to the extent they read on the elected regulatory region and plasmid(s) containing that regulatory region.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Sequence Rules***

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However,

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this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from claims 6 and 13, and in the specification, pg 3, line 19; pg 5, lines 2-3 and 29-30; pg 42, lines 21-22; pg 62, lines 23-24; pg 69, lines 21-33; pg 70, lines 1-15; pg 77, lines 23-25; pg 78, lines 2-3, 16 and 21-22; pg 80, lines 24-25; pg 81, lines 11-12; pg 83, lines 2-8; pg 84, lines 24-25; Table 2; and the legends of Figures 1-3, 9, 12, 19-20 and 28-34.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth above. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.

December 12, 2002

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180 / 1638

